DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 20, 2015

CareFusion Germany 234 GmbH
Mr. Elmar Niedermeyer
Regulatory Affairs
Leibnizstrasse 7
Hoechberg, Bavaria 97204
GERMANY

Re: K142959
Trade/Device Name: Vyntus Walk
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 11, 2015
Received: February 18, 2015

Dear Mr. Niedermeyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

(revised Indication for Use)
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Indications for Use

510(k) Number (if known): K142959

Device Name: Vyntus Walk

Indications for Use:

Vyntus Walk is a mobile medical application which is intended to be used on a mobile platform to collect and collate sequential pulse oximetry data during six minute walk tests (6MWT). Pulse oximetry data are collected from an external pulse oximeter, using Bluetooth connection. The mobile platform has access to a host computer with SQL database (SentrySuite) via a wireless network for further data evaluation and diagnosis. Patients as young as 4 years of age and older can be tested providing they can cooperate with the test instructions. Measurements are performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 26/09/2014

5.2 Submitter

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Oximeter
CFR 870.2700, Classification Product Code DQA

5.5 Trade Name

Vyntus Walk

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

74 Cardiovascular Part 870 Code DQA

5.8 Reason for Premarket Notification

- New Medical App

5.9 Legally predicate marketed devices

- SpiroPro K092324 Code DQA, BTY

5.10 Predicate Device Company

- VIASYS (now CareFusion Germany 234 GmbH)

5.11 Device Description

Description & function:

The Vyntus Walk is a tablet based software mobile application that collects and collates pulse oximeter data from an external pulse oximeter during a 6 Minute Walk Test and remotely transmits to the SentrySuite for access to physicians for diagnosis purposes. Vyntus WALK includes wearable, wireless sensors connected to a tablet PC running Android Operating System with a workflow driven 6MWT application. Vyntus WALK integrates seamlessly in today's mobile healthcare environment through the new Sentry CIS™ service landscape for central data management and reporting.

Scientific Concept:

The digital pulse oximeter measures both the oxygen saturation level and the heart rate of the patient continuously. This is transferred via Bluetooth to the tablet and is displayed graphically during the test with a date and time stamp. All data is stored together with the patient and test data in the repository database for later evaluation and printing.

Significant performance characteristics:

Medical APP for displaying, printing and transferring data.

Vyntus Walk App

Parameter	Measurement range	Accuracy
SpO2	0 to 100 %	acc. Nonin Oximeter
Heart rate (HR)	18 to 321 pulses per minute	acc. Nonin Oximeter
Manual entered data		
Lap distance	30m – 100m	N/A
Lap count	0 – 100	N/A
Duration of pauses	0 – 360s	N/A
Number of pauses	0 – 100	N/A
RPE scale	0 – 10	N/A

5.12 Intended Use Statement

Vyntus Walk is a mobile medical application which is intended to be used on a mobile platform to collect and collate sequential pulse oximetry data during six minute walk tests (6MWT). Pulse oximetry data are collected from an external pulse oximeter, using Bluetooth connection. The mobile platform has access to a host computer with SQL database (SentrySuite) via a wireless network for further data evaluation and diagnosis. Patients as young as 4 years of age and older can be tested providing they can cooperate with the test instructions. Measurements are performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities).

5.13 Required Components

- Android Tablet with Vyntus WALK APP
- Charger for Tablet PC
- US/AUS, European and UK Power Adapter
- USB cable
- Nonin 3150 Bluetooth Oximeter
- AAA Batteries for the pulse oximeter
- Instruction for Use Vyntus Walk
- Accessories

5.14 Summary Table of Comparison

Comparison Table		
	SpiroPro K092324	**Vyntus Walk** (proposed device)
Indications for Use	The SpiroPro is a portable, battery operated device and can be used by physicians in the office or hospital, in occupational medicine or by patients in the home. The SpiroPro measures inspiratory and expiratory lung function parameters in adults and children 4 years and older. In addition to the pulmonary function measurements, oxygen saturation and heart rate can be recorded.	Vyntus Walk is a mobile medical application which is intended to be used on a mobile platform to collect and collate sequential pulse oximetry data during six minute walk tests (6MWT). Pulse oximetry data are collected from an external pulse oximeter, using Bluetooth connection. The mobile platform has access to a host computer with SQL database (SentrySuite) via a wireless network for further data evaluation and diagnosis. Patients as young as 4 years of age and older can be tested providing they can cooperate with the test instructions. Measurements are performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities).
Target population	Adults and children 4 years and older	**similar**
Place of use	by physicians in the office or hospital, in occupational medicine or by patients in the home	**similar**
Energy used	Battery operated device	**similar**
Design	Medical device with firmware and Software	Medical APP operated on a tablet PC
Interface	RS232 & Bluetooth interface	WLAN & Bluetooth interface
Performance (measuring programs)	• 6 Minute Walk Test	**similar**
	• Slow Spirometry • Forced Spirometry	not applicable
Biocompatibility (Patient contacting parts)	• finger clip sensor • nose clip pad • single use mouthpiece	not applicable
Sterility	The device along with its accessories is neither supplied sterile nor intended to be sterilized	**similar**

Summary of technological characteristics compared to the predicate device to the table above:

- The Vyntus Walk is similar in indication for use compared to the predicate SpiroPro whereby the Vyntus Walk is more described in detail. The difference between SpiroPro and Vyntus Walk is that the predicate in addition can measure inspiratory and expiratory lung function parameters and the Vyntus Walk will only be used on a mobile platform. But for the 6 minute walk test and the subsequent diagnostic use, the Vyntus Walk is similar to the predicate SpiroPro. The Vyntus Walk operates as intended for the 6 minute walk test, is similar compared to the predicate and the differences are not critical to the predicate and do not affect the safety and effectiveness of these devices when used as labeled. The patient population of both devices is similar. It is 4 years and older and thereby the proposed device is substantially equivalent to the predicate device.
- The design of both devices is different. The predicate SpiroPro is a medical device with hardware, firmware and software, whereby the Vyntus Walk is a Medical App which will be operated on a tablet PC.
- The interface of Vyntus Walk is similar to the interface of the predicate SpiroPro. Both devices use a Bluetooth interface. In addition the Vyntus Walk uses WLAN for transferring the data to a workstation. The proposed device is substantially equivalent to the predicate device.
- The measuring program of the proposed device is similar to the predicate device SpiroPro. Both devices are used to collect and collate data during a the 6 Minute Walk Test. The Vyntus Walk is substantially equivalent to the predicate SpiroPro.

5.15 Summary of Device Testing

1. Non-clinical tests conducted for determination of substantial equivalence:

Characteristic	Standard/Test	Results Summary
1. Risk Management	ISO 14971	The proposed device passes the applicable tests and standards
2. Usability	EN 62366	The proposed device passes the applicable tests and standards
3. Software life cycle	ISO 62304	The proposed device passes the applicable tests and standards
4. 6 Minute Walk Test	ATS (6MWT)	The proposed device passes the applicable tests and standards
5. Accuracy Testing	Comparison bench testing with predicate device	The proposed device passes the applicable tests and standards
Summary Discussion of Bench Performance Data		
The CareFusion Vyntus Walk Medical App passed all specified test requirements. The validation and verification testing confirmed this device meets user needs and design inputs for a 6 Minute Walk Test. Testing also confirmed that device performance meet the requirements of the standards listed in the performance testing summary above. These standards address risk management, usability, software life cycle, ATS and accuracy testing. All testing which have been performed demonstrate substantial equivalence to the predicate device. Performance testing like Basic Safety, EMC Compatibility and Biocompatibility are not applicable as Vyntus Walk is a medical App only.		

2. Clinical tests conducted for determination of substantial equivalence and/or of clinical information:

Clinical Performance Data/Information: Clinical test document: **Validation Summary – Accuracy of Measures** Document ID: **671113 86**
Summary Discussion of Clinical tests conducted
The device was tested in September 2014. Heart rate and SpO_2 data have been obtained from a group of 16 healthy subjects who performed a 6 Minute walk test using the Vyntus Walk. The test was performed according to ATS criteria by walking a length of 30 meters per lap. • No adverse events or complications were reported during this testing. • The Vyntus Walk operates as intended and the results were substantially equivalent to the predicate device. Justification: The goal of the biological test performed was to receive accurate data for the performance of the device under natural environment.

3. Conclusion drawn from non-clinical and clinical data:

The Carefusion Vyntus Walk meets the functional claims and intended use as described in the product labeling. The Vyntus Walk is substantially equivalent to the predicate device described in the submission.

5.16 Conclusion

Based on the above, CareFusion concludes that the Vyntus Walk is substantially equivalent to the legally marketed predicate device.